AUG 2 1 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K010785

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact:

James A. Lee
Regulatory Affairs Specialist

Device Identification:

Common Name:
Vascular Clamps, and Endoscopic Instruments

Trade Name: (optional)
The KSEA Dion Gracia Set

Indication: The KSEA Dion Gracia set is intended for use by qualified surgeons in vascular surgery.

Device Description: The KSEA Dion Gracia set is comprised of manual surgical instruments. The body contact materials are surgical grade stainless steel.

Substantial Equivalence: The KSEA Dion Gracia set is substantially equivalent to the predicate devices since the basic design, dimensions, stainless steel, and intended uses are similar. The minor differences between the KSEA Dion Gracia set and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____

James A. Lee, Ph.D.
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2001

James A. Lee, Ph.D.
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600

Re: K010785
Trade Name: KSEA Dion-Gracia Set
Regulation Number: 21 CFR 870.4450
Regulatory Class: Class II (two)
Product Code: DXC
Dated: July 17, 2001
Received: July 18, 2001

Dear Dr. Lee:

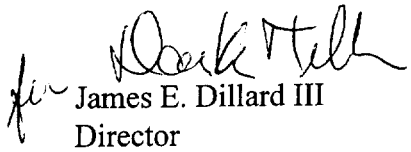
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010785

Device Name: KSEA Dion-Gracia Set

Indications for Use: The KSEA Dion-Gracia Set is intended for use by qualified surgeons in vascular surgery. The intended use for each component is as follows.

Elevators
The elevators are intended to elevate and manipulate tissue or vessels during vascular surgery.

Palpation Hook
The palpation hook is used to manipulate tissue, and aid in suturing and tying knots during vascular surgery.

CLICK*line* Forceps
The CLICK*line* DeBAKEY curved forceps and tunneling forceps with atraumatic tips are used primarily to hold, grasp or sequester tissue and other structures during vascular surgery.

CLICK*line* Suture Grasper and Knot Tier Forceps
The suture grasper and knot tier forceps are used to grasp suture and to aid in tying knots to close the surgical access area during and after completion of the vascular surgery.

CLICK*line* Scissors
The scissors are used primarily for dissecting and cutting tissue, and other structures during vascular surgery.

Vascular Cross Clamp Forceps
The Vascular Cross Clamp Forceps are intended for temporary cross-occlusion of arteries and veins during vascular surgery.

Laparoscopic Scalpel
The Laparoscopic Scalpel is intended use is for cutting tissue or other structures during vascular surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010785